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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/724,379	11/28/2003	Thomas Dietz	17127	9652
7590	05/02/2006		EXAMINER	
Leopold Presser Scully, Scott, Murphy & presser 400 Garden City Plaza Garden City, NY 11530			KUGEL, TIMOTHY J	
			ART UNIT	PAPER NUMBER
			1712	

DATE MAILED: 05/02/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/724,379	DIETZ, THOMAS	
	Examiner Timothy J. Kugel	Art Unit 1712	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 22 March 2006.
- 2a) This action is FINAL.      2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1,4,7,10 and 13-20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1,4,7,10 and 13-20 is/are rejected.
- 7) Claim(s) 19 and 20 is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:
1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
|  | 6) <input type="checkbox"/> Other: _____                                    |

**DETAILED ACTION**

1. Claims 1, 4, 7, 10 and 13-20 are pending as amended on 24 March 2006, claims 2, 3, 5, 6, 8, 9, 11 and 12 being cancelled.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

***Specification***

3. Applicant's amendment, filed 24 March 2006, with respect to the correction of informalities has been fully considered and are corrective.

The objection to the specification has been withdrawn.

***Claim Objections***

4. Applicant's cancellation of claim 8, filed 24 March 2006, renders the previously cited objection moot.

The objection to claim 8 has been withdrawn.

5. Applicant's amendment, filed 24 March 2006, with respect to the removal of the second period in claim 7 has been fully considered and are corrective.

The objection to claim 7 has been withdrawn.

6. Claims 19 and 20 are objected to because of the following informalities:

Claim 19 recites, "...said sphingoid base..." and should recite, "...said free sphingoid base..."

Claim 20 recites, "...adding an water-based..." and should recite, "...adding a water based..."

Appropriate correction is required.

***Claim Interpretation***

7. The amended limitation "...adding an additional auxiliary to a molten oil phase..." has been construed to be synonymous to and supported by "the emulsifier wax gels can be prepared by melting skin-identical sphingolipids with at least one emulsifier, at least one consistency-imparting agent and optionally additional auxiliaries" from ¶0043 of the instant specification.

***Claim Rejections - 35 USC § 112***

8. Applicant's cancellation of claim 8, filed 24 March 2006, renders the previously cited rejection under 35 USC § 112 2<sup>nd</sup> paragraph moot.

The rejection of claim 8 under 35 USC § 112 2<sup>nd</sup> paragraph has been withdrawn.

9. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

10. Claim 17 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

The amended limitation "...adding an additional auxiliary...or to a water phase." does not find support in the instant disclosure or original claims.

***Claim Rejections - 35 USC § 102 and 35 USC § 103***

11. Applicant's cancellation of claims 2, 3, 5, 6, 8, 9, 11 and 12, filed 24 March 2006, renders the previously cited rejection under 35 USC § 102 and 35 USC § 103 moot.

The rejection of claims 2, 3, 5, 6, 9, 11 and 12 under 35 USC § 102(b) as being anticipated by US Patent Application Publication 2002/0010215 (Shiroyama hereinafter) has been withdrawn.

The rejection of claim 8 under 35 USC § 103(a) as being unpatentable over Shiroyama in view of US Patent 6,362,142 (Weber hereinafter) has been withdrawn.

12. The rejection of claims 1, 4, 7, 10 and 13-18 under 35 USC 102(b) as being anticipated by Shiroyama is maintained. Applicant's amendment and arguments filed 24 March 2006 have been fully considered but they are not persuasive.

Applicant argues that Shiroyama does not teach a free sphingoid base, a water-based emulsifier wax gel, an oil-in-water emulsion or processes for making the gel or emulsion, particularly that Shiroyama teaches ceramides which differ from the claimed free sphingoid bases; further arguing that Shiroyama's teaching of phytosphingosine is from prior art improved upon by the Shiroyama process.

While applicant's argument is correct that Shiroyama's explicit disclosure of phytosphingosine is directed to improved-upon prior art, Shiroyama explicitly refers to ceramides synthesized by known processes such as that of Japanese Patent 7-165690. US Patent 5,665,778 (Semeria hereinafter) is an English language equivalent to Japanese Patent 7-165690 and discloses ceramides obtained by the claimed

sphingosine or sphinganine, which applicant's disclosure and original claims define as both ceramides and free sphingoid bases.

Since Shiroyama teaches the same components and the same processes as claimed, one of ordinary skill in the art at the time the invention was made would have expected that a water-based emulsifier wax gel and an oil-in-water emulsion respectively would inherently be formed as claimed.

13. New claims 20 is rejected under 35 U.S.C. 102(b) as being anticipated by Shiroyama.

Shiroyama teaches an aqueous ceramide composition (Abstract, ¶0001) comprising 1.0 to 5.0% by weight (Abstract, ¶0012) of a ceramide—including phytosphingosine (¶0004)—that are recovered from mammalian tissues (¶0030), 20:1 to 1:3 of the ceramide—which calculates to 0.05 to 15% by weight—of an nonionic or anionic surfactant (¶0046)—including polyoxyethylene sorbitan fatty acid esters, polyoxyethylene sorbitol fatty acid esters, polyoxyethylene glycerol fatty acid esters, polyoxyethylene fatty acid esters, polyoxyethylene (hydrogenated) castor oil derivatives and sucrose fatty acid esters and mixtures of two or more suitable surfactants (¶¶0042-0043), 0.5 to 2% of a fatty alcohol such as cholesterol (¶¶0048 and Example 5 Table 1 and Comparative Example 2 Table 2), 70 to 88% by weight of water (Examples 1-5 Table 1) and auxiliary components such as humectants (¶0056).

Shiroyama further teaches a process for preparing the above compositions comprising heating the components except the water to 80 to 120° C and adding to the water, mixing uniformly and cooling to 5 to 40° C (¶0060), and an oil-in-water emulsion

comprising the above composition at 5-25% by weight (Examples 9-18 ¶¶0067-0076 and Tables 4-5).

***Conclusion***

14. Applicant's amendment necessitated the new grounds of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Timothy J. Kugel whose telephone number is (571) 272-1460. The examiner can normally be reached 6:00 AM – 4:30 PM Monday-Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Randy Gulakowski can be reached on (571) 272-1302. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300..

Art Unit: 1712

16. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

TJK  
Art Unit 1712



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